

CLAIMS

1. A valve prosthesis for implantation in a body channel, the prosthesis comprising a collapsible valvular structure (14), and an
5 expandable frame (10, 10') on which said valvular structure (14) is mounted, said valvular structure (14) being composed of a valvular tissue compatible with the human body and blood, the valvular tissue being sufficiently supple and resistant to allow said valvular structure (14) to pass
10 from a closed state to an open state to allow a body fluid exerting pressure on the valvular structure (14) to flow, wherein said valvular tissue forms a continuous surface and is provided with guiding means formed or incorporated within, said guiding means creating stiffened zones which induce said valvular structure (14) to follow a patterned movement in its expansion to said open state and closed state, providing therefore a
15 structure sufficiently rigid to prevent eversion.

2. The prosthetic valve according to claim 1, wherein an internal cover (19) is coupled to the valvular structure (14) and placed between said valvular structure (14) and the internal wall of the structure of the frame (10) to prevent any passage of the body fluid through said structure.

20 3. A prosthetic valve according to claim 2, wherein the internal cover is extended in its lower end by an external cover rolled upon the external wall of the structure of the frame.

4. A prosthetic valve according to claim 2 or 3, wherein both the valvular structure (14) and the cover (19) are one piece.

25 5. A prosthetic valve according to claim 2 or 3, wherein the valvular structure and/or the cover are coated with or are made of an anti-thrombic substance.

6. A prosthetic valve according to claim 2, wherein the internal cover (14) covers the full length of the internal surface of the frame (10) or
30 only a part of said internal surface.

7. A prosthetic valve according to claim 1, wherein said valvular structure (14) has a substantially truncated hyperboloidal shape in its open state.

8. A prosthetic valve according to claim 1, wherein said guiding means comprise strips inclined from the base (15) to the upper extremity (16) of the valvular structure (14) when compared to the central symmetry axis (XX') of the valvular structure (14), the curvature of said guiding means being concave towards said upper extremity (16) to impart an helicoidal movement to the valvular structure (14) when compared to the central axis (XX') of the valvular structure (14).

9. A prosthetic valve according to claim 8, wherein said guiding means comprise inclined pleats extending from the base (15) of the valvular structure (14) to the upper extremity (16) of said valvular structure (14).

10. A prosthetic valve according to claim 8, wherein said guiding means comprise at least 3, strengthening struts (17, 21), formed from thickened zones or incorporated strips of stiffening material.

11. A prosthetic valve according to claim 7, wherein the strips are soldered or glued on the valvular tissue.

12. A prosthetic valve according to anyone of claims 1 to 7, wherein said guiding means are rectilinear (17) in plane including the central axis (X'X) from the basis (15) to the upper extremity (16) of the valvular structure (14).

13. A prosthetic valve according to claim 12, wherein said guiding means comprise pleats extending from the base (15) of the valvular structure (14) to the upper extremity (16) of said valvular structure (14).

14. A prosthetic valve according to claim 12, wherein said guiding means comprise at least 3 strengthening struts (17, 21), formed from thickened zones or incorporated strips of stiffening material.

15. A prosthetic valve according to claim 1, wherein said stiffened zones are main parts (23) of trapezoidal shape, preferably two main parts formed symmetrically with regard to the central axis (XX') of the valvular structure (14), separated by less rigid parts (24), and in that said guiding means are of a rectilinear type.

16. A prosthetic valve according to claim 15, wherein each of said main parts (23) occupies approximately one third of the circumference of the upper part of the valvular structure (14) when this latter is in its open position.

17. A prosthetic valve according to claim 15, wherein the main parts (23) are thickened zones and the other parts (24) are thinner zones.

18. A prosthetic valve according to claim 1, wherein stiffened zones are a continuous of rectangular shape, completed by a flexible and foldable part to constitute the valvular structure.

19. A prosthetic valve according to claim 1, wherein said valvular tissue is made of synthetic biocompatible material such as polyethylene or polyamide, or made of biological material as pericardium or porcine leaflets.

20. A prosthetic valve according to claim 1, wherein said valvular structure (14) is fastened to the frame (10) by sewing, by molding, soldering or by gluing, to prevent regurgitation of said body fluid between the frame (10) and the valvular structure (14).

21. A prosthetic valve according to claim 1, wherein said frame (10) is expandable from a size on the order of 4 to 5 millimeters to a size of 20 to 35 mm in diameter.

22. A prosthetic valve according to claim 1, wherein said frame (10), in its fully expanded form, has a height of approximately between 10 and 15 mm and in its fully compressed frame, a height of approximately 20 mm.

23. A prosthetic valve according to claim 1, wherein said frame (10) is made in material which is distinguishable from biological tissue by non invasive imaging techniques.

24. A prosthetic valve according to claim 1, wherein said frame (10) is a foldable plastic or stainless metal structure made of intercrossing, linear bars, preferably rounded and smooth.

25. A prosthetic valve according to claim 23, wherein the size and the number of the bars are determined to give both the maximal rigidity when said frame (10) is in its expanded state and the smallest volume when the frame (10) is in its compressed state.

26. A prosthetic valve according to claim 1, wherein the frame (10) has a concave shape comprising projecting curved bars at the extremities (12).

27. A prosthetic valve according to claim 1, wherein a first frame (10) is coupled with another frame (10') which has bars of size substantially lower than said first frame (10) and which is embedded inside this latter, along a common shaft (27), the first frame being compressed with a first balloon catheter (26) and the second frame (26') being a part of a prosthetic valve (13) according to claim 1, each frame squeezed on each of the two balloons in order to constitute a sequential double balloon catheter (40).

28. A double balloon catheter according to claim 27, to separately position a first frame to be introduced in the previously dilated stenosed aortic valve and place a second frame that comprises the valvular structure, this catheter comprising two balloons fixed on a catheter shaft and separated by a few millimeters, the first balloon to be introduced being sufficiently strong to avoid bursting even at a very high inflation pressure and aimed at carrying, in its deflated state, a strong frame aimed at scaffolding the previously dilated stenosed aortic valve, the second balloon being aimed at carrying the second frame with the valvular structure.

29. A double balloon catheter according to claim 27, to separately position a first frame to be introduced in the previously dilated stenosed aortic valve that comprise the valvular structure and place a second frame, this catheter comprising two balloons fixed on a catheter shaft and
 5 separated by a few millimeters, the first balloon being aimed at carrying the second frame with the valvular structure, a strong frame aimed at scaffolding the previously dilated stenosed aortic valve, the second balloon to be introduced being sufficiently strong to avoid bursting even at a very high inflation pressure and aimed at carrying, in its deflated state,

10 30. A double balloon catheter according to claim 27, having a shaft comprising two lumens for successive and separate inflation of each balloon and an additional lumen for passage of a guide wire.

31. A method of using a two-balloon catheter with a first frame and second frame to which a valve prosthesis according to claim 1 is fastened,
 15 wherein a valve implantation is performed comprising two immediately successive steps of:

1/ expanding and positioning a first frame by inflating a first balloon (26) at a high inflation pressure,

2/ expanding and positioning a valvular structure (14) inside the
 20 frame (10') using a second balloon (26'), wherein step (2) occurs within a few seconds after step 1 and wherein a total aortic regurgitation towards the left ventricle takes place in the time interval between the two steps as an hemodynamic condition that cannot be faced for more than a few heart beats, and wherein an expansion and positioning of the frame part (10') of
 25 the IV (13) is allowed using a strong pressure inflation of the balloon (26') without risking damaging the valvular structure (14) which needs only a light pressure inflation for its own expansion

32. A method according to claim 31, wherein a previous dilatation of the stenosed aortic valve is performed as an initial step of the procedure
 30 to prepare the distorted valve to facilitate the following steps:

1/ positioning the double balloon catheter (40) with the first balloon (26) with the frame at the level of the aortic annulus (2a), the second IV balloon (26') being inside the left ventricle beyond the aortic annulus (2a);

2/ compressing the stenosed aortic valve (1', 2') with the first
5 balloon (26), the balloon being inflated maximally up to the bursting point, to prepare the IV insertion, inflation lasting a few seconds with a powerful pressure to expand the frame and forcefully embed said frame in the remains of the dilated valve, pushing away remains of the previously dilated stenosed natural valve;

10 3/ deflating immediate said first balloon (26) and; the first frame (10) remaining attached to the stenosed valve (1', 2'), the catheter (40) is pulled back to position the IV balloon (26') inside the previously expanded frame (26);

15 4/ Immediately after being well positioned, the IV balloon (26') is promptly inflated, to expand the IV 13;

5/ when the IV 13 is blocked inside the first frame (10), the IV balloon (26') is deflated.